

CLAIMS

1. A hydrate of 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt., characterised in that it:
 - (i) comprises water in the range of from 0.2 to 1.1% w/w ; and
 - (ii) provides an infra red spectrum containing peaks at 764 and 579 cm⁻¹; and/or
 - (iii) provides an X-ray powder diffraction (XRPD) pattern substantially as set out in Figure II.
- 10 2. A hydrate according to claim 1, wherein the water content is in the range of from 05 to 0.6%w/w.
- 15 3. A hydrate according to claim 1 or claim 2, which provides an infra red spectrum substantially in accordance with Figure I.
4. A hydrate according to any one of claims 1 to 3, which provides an X-ray powder diffraction (XRPD) pattern substantially as set out in Figure II.
- 20 5. A hydrate according to any one of claims 1 to 4, in isolated form.
6. A hydrate according to any one of claims 1 to 5, in pure form.
7. A hydrate according to any one of claims 1 to 6, in crystalline form.
- 25 8. A compound in the form of a rehydratable form of a hydrate according to any one of claims 1 to 7.
9. A process for preparing a hydrate according to claim 1, characterised in that 5-[4-[2-(N-methyl-N-(2-pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione, maleic acid salt is crystallised from aqueous ethanol.
- 30 10. A process according to claim 11, wherein the aqueous ethanol contains from 2% to 2.5% of water by volume.
- 35 11. A pharmaceutical composition comprising an effective, non-toxic amount of a hydrate according to claim 1 and a pharmaceutically acceptable carrier therefor.

12. A hydrate according to claim 1, for use as an active therapeutic substance.
13. A hydrate according to claim 1, for use in the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof.
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14. The use of Hydrate for the manufacture of a medicament for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof.
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15. A method for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof, in a human or non-human mammal which comprises administering an effective, non-toxic, amount of Hydrate to a human or non-human mammal in need thereof.
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